Conductance sizing balloon for measurement of peripheral artery minimal stent area

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Background: **Because stent underdeployment occurs frequently, accurate minimal stent area (MSA) measurement during postdilatation is necessary. This study investigated the accuracy and repeatability for MSA determination using a novel conductance balloon (CB) catheter for peripheral vessels.**
Methods: **The CB catheter is a standard balloon catheter that measures electrical conductance (ratio of current/voltage drop) in real-time during inflation, which directly relates to the balloon cross-sectional area through Ohm's law. CB measurements were made in 4- to 10-mm phantoms on the bench, ex vivo in stents fully deployed in diseased human peripheral arteries, and in vivo in stents fully deployed in peripheral vessels in six swine. CB measurement accuracy and repeatability were calculated and compared with the known dimension (bench phantoms) or with intravascular ultrasound (IVUS) measurement after stent deployment (ex vivo and in vivo).**
Results: **CB measurements were highly accurate (error: 1.8% bench, 5% ex vivo, and 5% in vivo) and repeatable (error: 0.9% bench, 1.8% ex vivo, and 1.3% in vivo), with virtually no bias (average difference in measurements: −0.05 mm bench CB vs known phantom diameters, −0.06 mm ex vivo CB vs IVUS, and −0.11 mm in vivo CB vs IVUS).**
Conclusions: **The CB sizing capability can be integrated within a standard balloon catheter (two-in-one function) to provide accurate, real-time assessment of MSA to ensure full stent apposition rather than the use of pressure as a surrogate for size. (J Vasc Surg 2014;60:759-66.)**

Clinical Relevance: **Clinically, stent underdeployment is likely given that the expected balloon dimension is often not reached in vivo (ie, pressure/diameter relationships supplied by the manufacturer are inaccurate in vivo). The conductance balloon device described here serves as a standard postdilatation balloon with additional real-time, accurate, dimensional feedback. Balloon usage could eliminate the need for multiple inflations and potentially help with complications related to balloon underinflation and stent recoil, including in-stent restenosis, stent thrombosis, and revascularization. The future use of the technology could expand beyond peripheral postdilatation to other balloon applications, including coronary postdilatation, drug-eluting, cutting, cryoplasty, and valvuloplasty balloons.**

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Stenting during percutaneous arterial intervention has become the standard care for patients with symptomatic peripheral artery disease.[1,2] Stent underdeployment, defined as failure to have full strut apposition, occurs in 40% of percutaneous peripheral interventions.[3,4] There are even higher reported rates (70%-85%) during percutaneous coronary intervention when a more comprehensive definition of underdeployment, defined as expansion <90% of the expected minimal stent diameter or failure to have full strut apposition with <80% to 90% of the expected minimal stent area (MSA), is used.[5-8] The inability to achieve adequate deployment with full stent apposition impacts in-stent restenosis rates, in-stent thrombosis formation, and target vessel revascularization rates.[3,9,10]

The reasons for stent underdeployment have been rigorously evaluated in coronary interventions but to a much lesser extent in peripheral vessels. Studies have shown the major culprit is related to balloon underexpansion and device recoil related to plaque and the vessel wall or the stent metal.[11] On the other hand, underdeployment occurs regardless of stent type (both bare-metal and drug-eluting stents), stent dimension, manufacturer, deployment location in the vasculature, percentage of stenosis, and lesion length.[7,8,12,13]

Because stent underdeployment is well documented, balloon postdilatation is often used to achieve appropriate

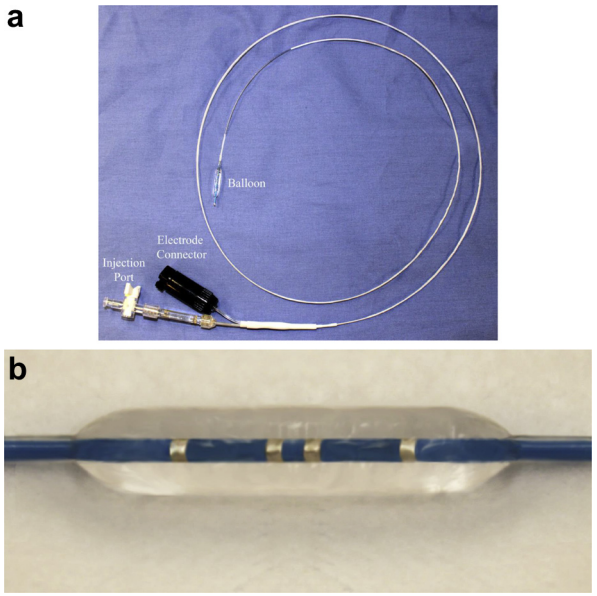

Fig 1. a, An example of a conductance balloon (CB) catheter shows the balloon at the distal end and the injection port and electrode connector at the proximal end. **b,** This specific catheter contains a 5-mm-diameter, 24-mm-length balloon with electrode spacing of 4, 1, and 4 mm between consecutive electrodes inside the balloon.

MSA and ensure stent apposition in peripheral and coronary vessels. Even when postdilatation is used with intravascular ultrasound (IVUS) guidance, a large percentage of stents still remain underdeployed.[14] This is not unexpected, however, because postdilatation balloons rely on ex vivo-derived manufacturer pressure compliance charts that do not accurately reflect the in vivo balloon pressure/diameter relationship.[11] Therefore, an integrated balloon-sizing technology may be useful to aid in accurate postdilatation sizing for the achievement of proper MSA and stent apposition in peripheral arteries. Here, a conductance balloon (CB) catheter is validated that provides real-time, quantitative, accurate, and repeatable conductance measurements for MSA sizing on the bench, ex vivo taken from diseased human peripheral artery specimens, and in vivo in the peripheral arteries in swine.

METHODS

The CB catheter (Fig 1) is a standard balloon catheter with a fluid port for inflation and an opening for wire exchange. The CB catheter contains four radiopaque electrically conducting electrodes inside the balloon. The outer two electrodes serve as the typical angiographic markers on the edges of the balloon, whereas the inner two electrodes mark the location of the sizing measurement inside the balloon. The spacing between the outer electrodes was generally 20 mm with 1- to 2-mm inner electrode spacing. The CB catheters tested had balloon diameters of 4 to 10 mm, balloon lengths of 24 to 100 mm, and catheter lengths of 80 to 150 cm. The balloon material was made of a noncompliant or semicompliant nylon or urethane material. The four distal electrodes inside the balloon were connected to a proximal electrode section that was connected to a computer console by a connector cable. A small amount of alternating current was injected through the outer electrodes at the distal end of the balloon, while the real-time conductance measurements for sizing were made across the inner two distal electrodes and displayed on the console screen. A detailed description of the physical laws that govern the CB operation is shown in the Appendix.

Bench validation. The accuracy and repeatability of CB balloon sizing measurements were tested on the bench. All CB catheters were individually calibrated in variously sized phantoms of uniform diameter using a 75%/25% mixture of saline and contrast (ie, 75% of 0.9% NaCl solution; Baxter Healthcare, Deerfield, Ill; and 25% of Omnipaque contrast, 350 mg/mL; GE Healthcare, Waukesha, Wisc).

After calibration, each CB catheter was randomly and repeatedly placed in another set of uniform phantoms, the conductance was recorded, and the cross-sectional area (CSA)/diameter was calculated according to Equations 1 and 2 (Appendix). Measurement accuracy was determined as the difference between the CB catheter and the true phantom measurement, and repeatability was determined as the difference between two randomized repeat CB catheter measurements. The true size of the phantoms was determined using a set of M1-M2 fixed gauges (Meyer Gauge Company Inc, South Windsor, Conn).

An identity plot was created for the accuracy (CB catheter vs true) and repeatability (CB catheter measurement 1 vs 2) data. A Bland-Altman analysis was used to assess the CB catheter measurements compared with the actual dimension.[15] The average, standard deviation, and root mean square (RMS) error were calculated for the accuracy and repeatability measurements.

Ex vivo human validation. CB catheter measurements were made ex vivo in four diseased human common and superficial femoral arteries with nonuniform, calcified lumen geometries. The specimens were taken from two male patients with severe peripheral arterial disease and accompanying ulcerations on the lower leg and foot that necessitated an amputation above or below the knee. All specimens were obtained with permission and approval of the local Institutional Review Board at Wishard Hospital (Indianapolis, Ind).

After the specimen was isolated, access to the vessel lumen was established and four peripheral stents (Express or Express LD; Boston Scientific, Natick, Mass; and Palmaz Genesis; Cordis, Bridgewater, NJ) were deployed. The initial sizing assessment made angiographically and with IVUS (Visions PV 018 Catheter; Volcano Corp, San Diego, Calif) showed evidence of nonuniform stent expansion requiring and thus leading to subsequent postdilatation.

The CB catheter was advanced, and at least four repeat measurements were made in each stent. Sizing

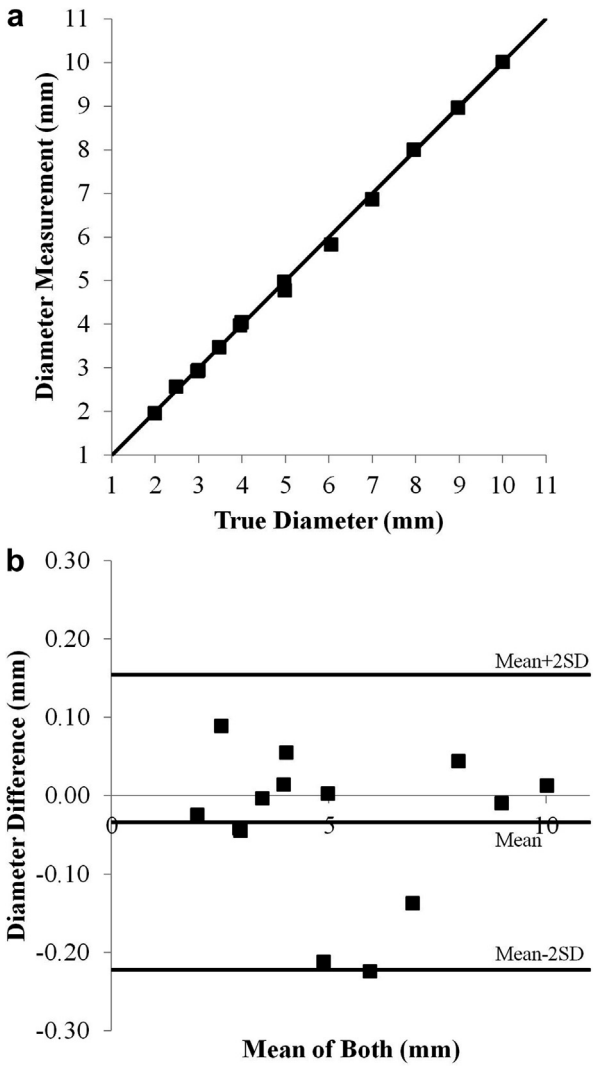

Fig 2. Bench accuracy for conductance balloon (CB) catheter sizing is shown in phantoms with diameters of 4 to 10 mm. The plots show **(a)** the identity relationship between the balloon measurement and the true dimension, with the *solid black line* as the identity line, and the **(b)** Bland-Altman analysis. *SD,* Standard deviation.

measurements using the CB catheter were based on Equations 1 and 2 (Appendix). Subsequent to CB measurements, an IVUS measurement was made for accuracy validation. CB catheter accuracy was based on a comparison with IVUS, and repeatability was based on consecutive CB measurements. A linear regression, Bland-Altman, and RMS analysis were all completed for the ex vivo data as in the bench analysis.[15]

In vivo animal validation. In vivo validation using the CB catheter was performed in six healthy domestic swine (58 ± 18 kg). Before each procedure, the CB catheter was calibrated in appropriately sized phantoms for each balloon in a water bath heated to body temperature (~37°C). Animals were sedated using an intramuscular injection of TKX (4.4 mg/kg), consisting of Telazol (50 mg/mL; Zoetis, Florham Park, NJ), ketamine (25 mg/mL), and xylazine (25 mg/mL), and maintained on a stable anesthetic plane through intubation and ventilation with 100% oxygen and 1% to 2% isoflurane. A sheath was placed for access to the carotid or iliac arteries.

An initial sizing assessment was made for each vessel (carotid or iliac) using IVUS (Visions PV 018 Catheter). This sizing assessment was used to select a stent with a dimension at or slightly greater than the measured IVUS assessment and deployed according to the manufacturer specifications (Omnilink; Abbott, Abbott Park, Ill; Boston Scientific Express and Express LD; and Visi-Pro; ev3 Endovascular Inc, Plymouth, Minn). After deployment, an IVUS measurement was made, followed by four repeat CB catheter sizing measurements (ie, complete inflations, followed by deflations). On the basis of standard interventional practice, the CB catheter measurements were made after end inflation ≤10 seconds in the carotid artery and ≤20 seconds in the iliac artery. The CB catheter was removed from the vessel, and the IVUS catheter was placed inside the stent to make the gold standard measurement of the stent size.

Similar to the ex vivo experiments, the accuracy of the CB catheter measurements (Equations 1 and 2 in the Appendix) was determined relative to IVUS measurement after stent deployment. Consecutive CB catheter measurements were used to make paired in vivo repeatability measurements for each stent. A least squares fit, Bland-Altman, and RMS analysis were used for the in vivo analysis, similar to the bench and ex vivo analyses.[15]

The animal procedures, including euthanasia at the end of the study, were completed with the approval of the Indiana University–Purdue University Indianapolis Institutional Animal Care Use Committee and followed the recommendations from the Animal Welfare Act, Institute of Laboratory Animal Research guidelines, and the Public Health Service policy.

RESULTS

The mean difference between the CB catheter diameter measurements and the true diameter on the bench was −0.05 ± 0.11 mm with an RMS error of 1.8% (accuracy, Fig 2, *a* and *b*) and a relationship between the measured and true dimension of $y = 0.99x$; $R^2 = 1$ (y = CB catheter-measured diameter and x = true diameter; Fig 2, *a*). For the repeatability analysis, the mean difference between repeat measurements was 0.01 ± 0.06 mm, with an RMS error of 0.9% (repeatability, Fig 3, *a* and *b*) and a repeatability relationship of $y = 1.0x$; $R^2 = 1$ (y = CB diameter measurement 2 and x = CB diameter measurement 1; Fig 3, *a*).

For each CB measurement, the system displayed the real-time temporal change in conductance during inflation (Fig 4, *a*), which was confirmed with fluoroscopy for the ex vivo and in vivo measurements (Fig 4, *b*). The outer marker electrodes provided visual confirmation for the

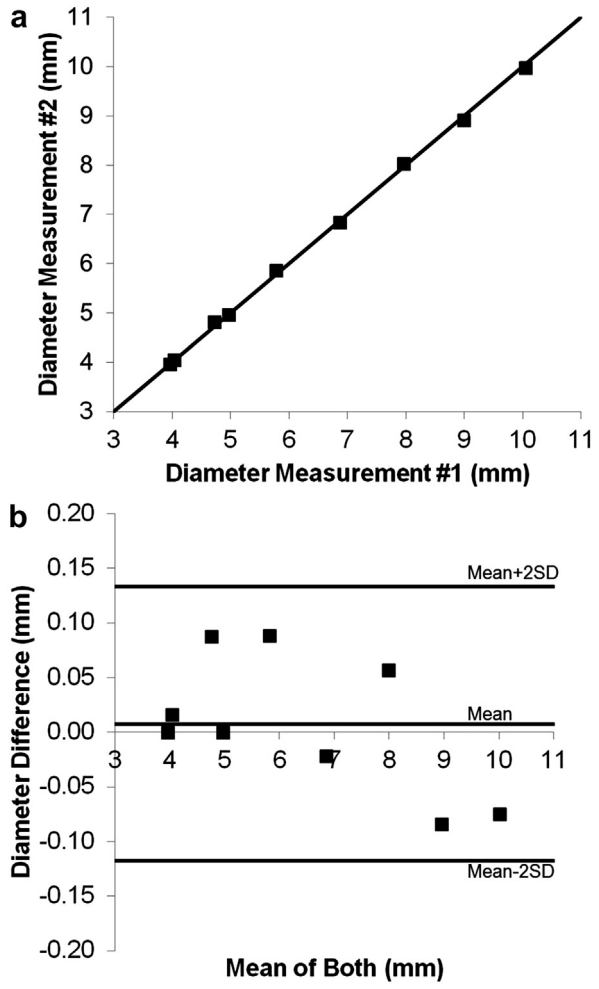

Fig 3. Bench repeatability for conductance balloon (CB) catheter sizing is shown in phantoms with diameters of 4 to 10 mm. The plots show **(a)** the identity relationship between repeat measures, with the *solid black line* as the identity line, and **(b)** the Bland-Altman analysis. *SD,* Standard deviation.

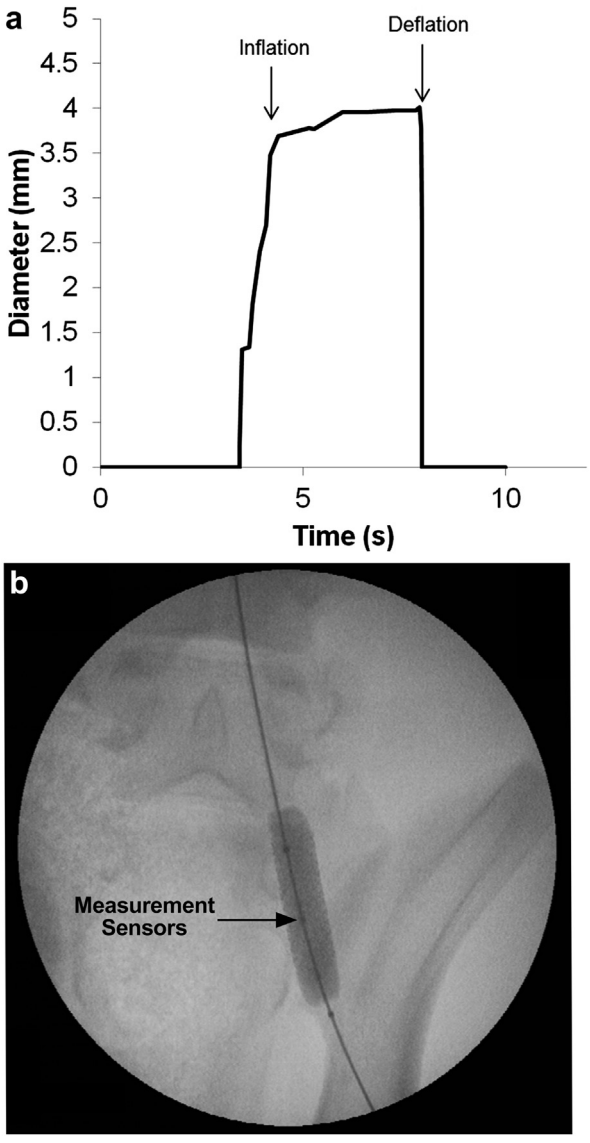

Fig 4. a, An example is shown of the temporal course of the conductance balloon (CB) catheter diameter/conductance measurement during inflation and deflation. **b,** A cine image shows a CB catheter during dilatation in vivo in an iliac stent in swine.

outer limits of the CB catheter, the inner marker electrodes were positioned and visualized in the desired location in the stent, and the balloon contour was visible during the inflation with the saline/contrast mixture (Fig 4, *b*).

The ex vivo CB catheter accuracy vs the IVUS measurement was −0.06 ± 0.30 mm, with 5.2% RMS error (open circles in Fig 5, *a* and *b*) and CB catheter repeatability was 0.01 ± 0.10 mm with 1.8% RMS error (open circles in Fig 6, *a* and *b*). The ex vivo accuracy relationship was $y = 0.98x$; $R^2 = 0.97$ (where y = CB catheter-measured diameter and x = IVUS-measured diameter; Fig 5, *a*), whereas the ex vivo repeatability relationship was $y = 1.0x$; $R^2 = 1.0$ (where y = CB catheter measurement 2 and x = CB catheter measurement 1, Fig 6, *a*).

In terms of in vivo accuracy (solid squares in Fig 5, *a* and *b*), the CB catheter and IVUS measurements had a mean difference of −0.11 ± 0.35 mm, an RMS error of 4.9%, and a linear accuracy relationship of $y = 0.98x$; $R^2 = 0.98$ (where y = CB catheter-measured diameter and x = IVUS-measured diameter, Fig 5, *a*). For in vivo repeat measurements (solid squares in Fig 6, *a* and *b*), the CB catheter had a mean difference of −0.02 ± 0.08 mm, an RMS error of 1.3%, and a linear repeatability relationship of $y = 1.0x$; $R^2 = 1$ (where y = CB catheter measurement 2 and x = CB catheter measurement 1, Fig 6, *a*). Before in vivo CB measurements, stents were underdeployed to 87% ± 7% of the nominal value, despite inflation, according to the manufacturer's specifications (manufacturer-predicted diameter: 7.99 ± 2.01 mm vs actual IVUS diameter: 6.98 ± 2.04 mm for in vivo stents).

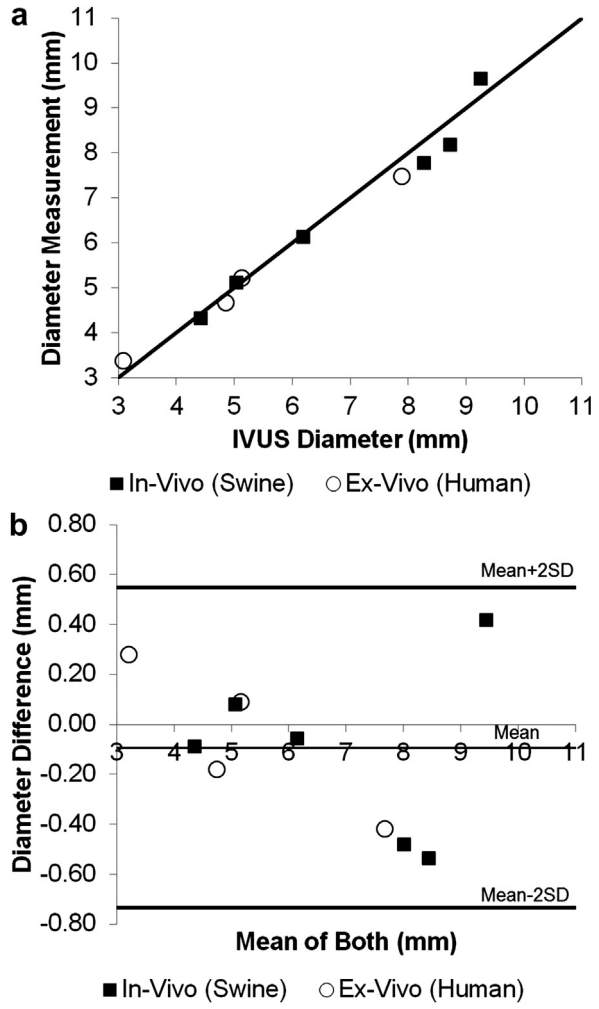

Fig 5. In vivo swine (*solid squares*) and ex vivo human (*open circles*) conductance balloon (CB) accuracy is shown. **a,** The identity relationship between the CB measurement and the intravascular ultrasound (*IVUS*) dimension, with the *solid black line* as the identity line. **b,** The Bland-Altman analysis shows the mean ± two standard deviation (*SD*) lines for the in vivo analysis only.

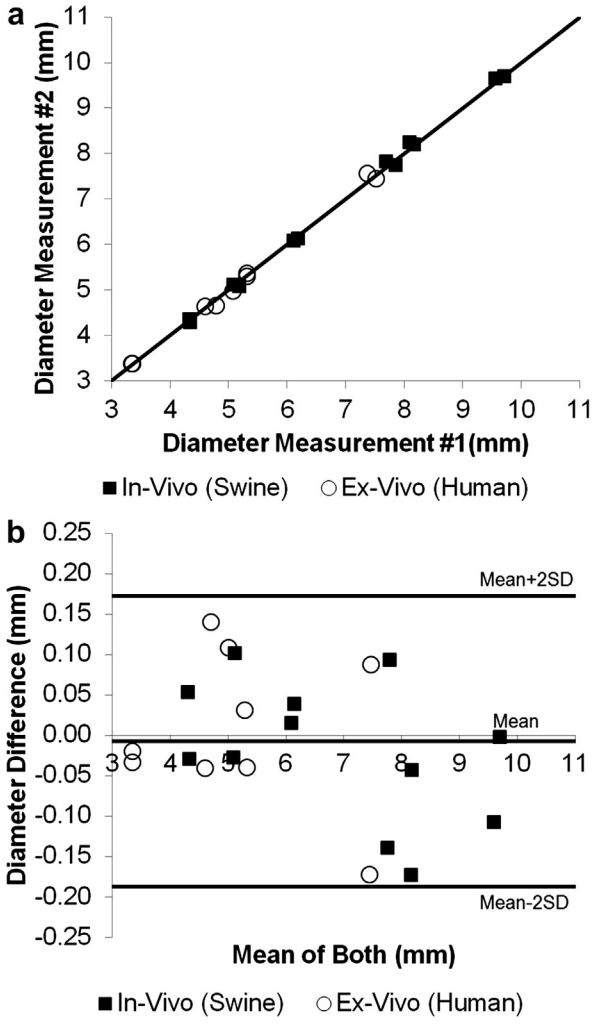

Fig 6. In vivo swine (*solid squares*) and ex vivo human (*open circles*) conductance balloon (CB) repeatability is shown. **a,** The identity relationship between repeat measures, with the *solid black line* as the identity line. **b,** The Bland-Altman analysis shows the mean ± two standard deviation (*SD*) lines for the in vivo analysis only.

DISCUSSION

The CB catheter system provided highly accurate and reproducible MSA sizing measurements. There was excellent agreement of the CB catheter measurements with the true lumen dimension on the bench (~2%), ex vivo (~5%), and in vivo (~5%), excellent repeatability (≤2% for bench, ex vivo, and in vivo), and a nearly perfect linear relationship ($R^2 = 1$) for each accuracy and repeatability analysis (Figs 2-6).

The reason for the high CB catheter accuracy and repeatability was due to the underlying fundamental physical basis for the technology (Ohm's law, Equation 1 in the Appendix) and the insulative nature of the balloon environment compared with inaccurate bench-derived manufacturer pressure/diameter relationships.[11] Because the distal electrodes are effectively insulated by the balloon and no current is lost to the surrounding environment (ie, the balloon acts like a phantom), the Ohm's law relationship provides a direct relationship between CSA and measured conductance. The conductance measurements directly relate to the CSA of the balloon at the measurement electrodes and do not require a cylindrical balloon assumption for accurate results (ie, conductance measures CSA directly, not diameter directly).

This was evidenced by the fact that virtually no difference in accuracy (~5%) or repeatability (1.5%-1.8%) existed between normal in vivo swine vessels with circular cross-sections and the ex vivo diseased human artery specimens with nonuniform geometries. The CB catheter showed highly accurate sizing across various diameters

(4-10 mm), anatomic locations (carotid, iliac, and femoral arteries), stent types, and balloon dimensions. Thus, based on Ohm's law and the insulative nature of the balloon environment, the CB catheter gives accurate and repeatable sizing results no matter the vessel or stent size, location, or disease state.

CB catheter accuracy vs the IVUS measurement in vivo was excellent, with an average (−0.11 mm) and standard deviation (−0.35 mm) that was appropriate given the full-millimeter step resolution that exists for peripheral stents. The ex vivo and in vivo accuracy (∼5%) was small but was larger than the bench accuracy (∼2%). This error was unlikely due to recoil, because the accuracy differences between the CB catheter and IVUS measurements were both positive and negative, with the average bias being negative, which means CB catheter measurements are smaller than IVUS measurements and thus cannot be due to recoil.

However, the slightly larger ex vivo and in vivo error may be due to other factors, including the inherent error introduced by the subjective IVUS measurements that is not present with the bench studies. This study used a 75/25 mixture ratio of saline and contrast; however, different mixture ratios can be used to produce the same precise sizing results if the unique mixture ratio and fluid conductivity is known and included in the system.

No accurate method currently exists for real-time quantitative MSA determination during peripheral interventions. Angiographic assessment (with marked wires/catheters) and pressure surrogates during balloon expansion provide inaccurate cross-sectional estimates for device dimension and, thus, may require multiple postdilatations and IVUS confirmations to achieve the desired MSA.[14] Pressure/volume relationships have been used for sizing in peripheral balloon catheters (eg, Metricath, Neovasc, Richmond, BC, Canada), but these systems have limited accuracy because they provide an average balloon size rather than a precise, focal sizing measurement, as with the CB catheter.[16]

Other studies have placed IVUS or optical coherence tomography transducers inside balloons.[17,18] With IVUS or optical coherence tomography inside a balloon, the MSA during inflation requires user interpretation (ie, not real-time sizing measurements) and requires the catheter to increase in size to accommodate the transducer and the balloon, which is a practical limitation, especially for other balloon applications such as coronary postdilatation. However, the CB catheter provides real-time, objective sizing that can be made to current standard peripheral or coronary catheter sizes.

The CB catheter can be used as a standard balloon catheter that provides an additional highly accurate and reproducible measurement during inflation, which allows the interventionalist to adjust the degree of expansion in real-time (not possible with standard balloons), eliminates the need for gradual dilatation(s), reduces X-ray exposure, and may eliminate the need for additional IVUS evaluation. The CB can also be used to avoid possible barotrauma to the vessel intima from hyperinflation or prolonged balloon inflation. The use of the CB catheter allows for the desired MSA to be achieved without overexpansion, which is important for current stents and clinical trials involving bioresorbable scaffolds, which are more fragile than metal stents and have strict restrictions related to overexpansion.[19,20]

The CB catheter can also aid in the treatment of bifurcation lesions to ensure that the bifurcation dimensions (each of the three branches) obey design laws in addition to stent apposition and MSA.[21] Chronic total occlusions can also be treated more adequately using the CB catheter because these lesions are the most difficult in which to achieve appropriate postdilatation and would benefit greatly from real-time feedback about balloon dimension, which allows the physician to adjust inflation instantaneously or deliver another therapy. The CB catheter can be easily extended for other applications, including sizing for stent delivery balloons, drug-eluting balloons, cutting balloons, cryoplasty, valvuloplasty, and coronary postdilatation.[22-25]

No adverse events were seen during in vivo device usage, and no long-term safety concerns are expected due to the small alternating current and the insulative nature of the balloon. Obviously, the next logical step is for future studies for CB safety and efficacy in vivo in diseased human arteries.

In general, interventionalists place the center of the balloon at the center of the underdeployed stent region. Thus, placing the sensors at the center of the balloon and making a single measurement are appropriate in many cases. The current spacing of the inner measurement sensors was 1 to 2 mm, which implies that the balloon CSA measurements are averaged across an effective length along the lesion of 1 to 2 mm, which is adequate resolution for focal lesions. In some instances, however, interventionalists may only use the balloon edge for dilatation, in which case, a measurement in the balloon center will not accurately reflect the dimension at the region of interest on the balloon edge if the balloon does not expand uniformly. In the case of very long lesions, where size of balloon expansion is needed along the length of the lesion, the CB catheter can be used with multiple sensors for simultaneous measurements along the length of the balloon to create a real-time measurement profile of the balloon dimension. This is feasible because sensors can be placed off center and still maintain high calibration accuracy (data not shown).

The CB catheter achieves accurate MSA and stent apposition by addressing the two known factors that affect deployment: balloon underexpansion and stent recoil due to the device or the vessel, or both.[11] Balloon underexpansion is addressed with use of the CB catheter due to the accurate, real-time sizing accomplished through conductance measurements during inflation that does not depend on ex vivo-derived pressure compliance tables.[7,8,11] Thus, when balloon underexpansion occurs, the CB catheter provides instantaneous feedback to the physician that more

pressure/volume is required to inflate the balloon beyond what was normally predicted by the manufacturer's compliance charts. In the case that the balloon is not fully expanded even at the maximum recommended inflation pressure, other therapy options, such as a larger balloon, are required. If the amount of recoil due to the stent itself is known, then the CB catheter can achieve the desired MSA by expanding to larger diameters that account for the stent recoil. Hence, the catheter provides confirmation that stent apposition occurs in cases of vascular/plaque recoil.

CONCLUSIONS

The CB catheter is a balloon catheter with additional sizing functionality that is not currently available clinically (potential two-in-one functions). The CB catheter allows for clinically accurate, real-time feedback that can deliver more effective therapy (potentially decrease stent restenosis and thrombosis) and thus possibly eliminate the need for multiple sizing and balloon inflations.

AUTHOR CONTRIBUTIONS

Conception and design: MS, AS, BC, GK
Analysis and interpretation: MS, AS, DB, GK
Data collection: MS, GA, AT, MB
Writing the article: MS, GK
Critical revision of the article: MS, GA, AS, BC, AT, MB, DB, GK
Final approval of the article: MS, GA, AS, BC, AT, MB, DB, GK
Statistical analysis: MS
Obtained funding: GK
Overall responsibility: GK

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APPENDIX

Mathematical and theoretical background for conductance balloon operation

During balloon inflation, the voltage, and in turn, the conductance measurement made inside the balloon can be used to determine the balloon dimension based on a physical law (ie Ohm's Law, Equation 1 below). Ohm's Law states that when a current flows through a resistor, the cross-sectional area (CSA) of the resistor is equal to the measured conductance (G) across the resistor times the length of the resistor (L) divided by the electrical conductivity of the resistor medium (σ), namely:

$$(1)\ CSA = \frac{GL}{\sigma}$$

In the case of the conductance balloon (CB) catheter, the fluid inside the balloon (a saline and contrast mixture) is the "resistor medium." G is measured across the inner electrodes, L is the known distance between the inner electrodes, and σ is the known electrical conductivity inherent to the saline/contrast medium inside the balloon. Because all of the variables on the right side of Equation 1 are known or are measured during inflation, the balloon CSA (Equation 1) and effective diameter (D) are directly related to changes in G as follows:

$$(2)\ D = \sqrt{\frac{4GL}{\pi\sigma}}$$

The σ of the fluid medium inside the balloon is determined before the procedure from calibration. Calibration measures G inside the CB catheter in various phantoms of known CSA in an appropriate size range for each balloon (eg, a 6-mm-diameter CB catheter was calibrated in phantoms from 4 to 6 mm). The slope of the G vs CSA/L relationship is the σ for the mixture of saline and contrast used to inflate the balloon.[26-29]